from Current Protocols in Molecular Biology ("CPMB"), in which an SDS-PAGE gel with a protein is homogenized and injected into mice in order to produce immune spleen cells for hybridoma fusions.

Applicants would like to thank the examiner for the courteous interview of August 19, 2002, where this rejection was discussed. Examiner Nolan cited a definition for "inert" that he obtained from Webster's. This definition was denoted as being in the context of chemical compounds, and defined "inert" compounds as being "non-reactive." During the interview, the undersigned urged that "inert" in the context of a biological system would more appropriately be defined as a substance that did not produce an adverse effect *in vivo*. Examiner Nolan conceded that this definition was appropriate, but cautioned that any showing of *in vivo* "inertness" would have to be for an amount corresponding to the amount that was used in the supporting CPMB excerpt.

After the interview, the undersigned again reviewed the CPMB excerpt, and noted that page 11.4.4 cautions that "mice immunized repeatedly with polyacrylamide tend to form adhesions that can make aseptic removal of the spleen difficult." Clearly, SDS-PAGE gel is not "inert" when used *in vivo* in the amounts specified in the CPMB excerpt. While the adhesions observed may be acceptable in a laboratory context, they certainly do not support the interpretation that SDS-PAGE gel is a pharmaceutically inert carrier, as recited in claims 76, 86, and 95. Reconsideration and withdrawal of the rejection under Section 102(b) based on Glass *et al.* is respectfully requested.

Claims 76, 86, 90, 91 and 97-109 are rejected under the first paragraph of Section 112. Examiner Nolan urges that the applicant has no written support for the subgenus claim inert pharmaceutical carrier as recited in these claims. This term is supported by the disclosure at the top of page 20 ("in association with an inert pharmaceutical vehicle"). Reconsideration and withdrawal of this ground of rejection is requested.

Claims 76, 86, 90, 91 and 100 are rejected under Section 103(a) based on Glass *et al.* in view of CPMB and Lerner *et al.* (newly cited). Examiner Nolan argues that

> the claimed invention differs from the prior art teaching(s) (only) in claims 90, 91 and 100 by the recitation(s) of a method of stimulating an immune response from a patient with the isolated protein in an inert pharmaceutical carrier for parenteral administration. However, CPMB teaches the stimulation of antibody response in mice with isolated proteins on SDS-PAGE gels. Lerner teaches the making of antibodies from known polypeptides, where the antibody can have predetermined specificity. Lerner also teaches that antibodies are useful in studying protein conformation of the protein.

As noted above, the SDS-PAGE gel of Glass *et al.* cannot be considered an "inert" pharmaceutical carrier as presently claimed. The rejection under Section 103(a) also must fail.

Applicants respectfully submit that all of the pending claims are now in condition for allowance. An early notice to this effect is earnestly solicited. If there are any questions regarding the application, the examiner is invited to contact the undersigned at the telephone number below.

Respectfully submitted,

23 September 2002
Date

By: for Barbara A. McDowell
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Should additional fees be necessary in connection with the filing of this paper, or if a petition for extension of time is required for timely acceptance of same, the Commissioner is hereby authorized to charge Deposit Account No. 19-0741 for any such fees; and applicant(s) hereby petition for any needed extension of time.